DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Food and Drug Administration

21 CFR Parts 556 and 558

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New Animal Drugs; Laidlomycin

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AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for the establishment of a tolerance for residues of laidlomycin in cattle liver. The previously established acceptable daily intake (ADI) for total residues of laidlomycin is also being codified.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 141–025 for use of CATTLYST (laidlomycin propionate potassium) Type A medicated articles used to formulate Type C medicated feeds for cattle. The supplemental NADA provides for the establishment of a tolerance for residues of laidlomycin in cattle livers. FDA is also taking this opportunity to codify the previously established ADI for total residues of laidlomycin. The supplemental NADA is approved as of May 12, 2003, and parts 556 and 558 (21 CFR parts 556 and 558) are amended

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by adding new § 556.346 and by revising § 558.305. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556–TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.346 is added to read as follows:

§ 556.346 Laidlomycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of laidlomycin is 7.5 micrograms per kilogram of body weight per day.

(b) *Tolerance.* The tolerance for parent laidlomycin (the marker residue) in the liver (the target tissue) of cattle is 0.2 part per million (ppm).

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.305 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e); and by adding new paragraph (c) to read as follows:

§ 558.305 Laidlomycin.

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(c) *Tolerances.* See § 556.346 of this chapter.

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Dated: 7/7/03

July 7, 2003.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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